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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,616	01/22/2004	Luisa Hernandez-Ramirez	91349	5023

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EXAMINER	
SIMMONS, CHRIS E	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
07/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,616	HERNANDEZ-RAMIREZ ET AL.	
	Examiner	Art Unit	
	CHRIS E. SIMMONS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/24/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,13 and 15-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,13 and 15-22* is/are rejected.

7)☒ Claim(s) *15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 15 is objected to because of the following informalities: the claim refers to claim 14, which is canceled. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 13, 15, 17, 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cipla (Cipla: Therapeutic Index: Gynecological Products: Forcan TZ KIT: Fluconazole and Tinidazole: 2000). It is assumed that claim 15 is meant to depend from claim 13.

The reference discloses a kit containing separate tablets of fluconazole (150mg) and tinidazole (2g). The tablets are administered as a one-time dose for the treatment of several vaginal infections. The reference further discloses that each of the ingredients is known as an antimicrobial and their combination is useful in the management of vaginal candidiasis, vaginal trichomoniasis, and bacterial vaginosis. The reference does not expressly teach less than 150 mg of fluconazole and less than 2000 mg tinidazole in a single composition.

Generally, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.05. Conversely, there is no evidence in the record establishing the Applicant's combination

of agents is any more effective or in any way different than any single member of that combination. Therefore, it would have been obvious to one of ordinary skill in the art to make a single tablet containing fluconazole and tinidazole. Further motivation for doing so would be to make a single tablet of fluconazole and tinidazole for easier administration since both ingredients can be taken as one single tablet instead of several tablets. Decreasing the amounts while maintaining the ratio would aid to minimize the size of the tablet for easier administration

As for claims 17-22, any differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine optimal amounts. See MPEP 2144.05 [R-5]. In claims 21 and 22, the ratio of each ingredient is exactly the ratio of the prior art – the amounts are simple decreased. This would also be desirable in order to minimize the size of the pill taken by the patient.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cipla (Cipla: Therapeutic Index: Gynecological Products: Forcan TZ KIT: Fluconazole and Tinidazole: 2000) in view of USP 5,660,860.

The disclosure and the rationale for the use of the primary reference are outlined above. The reference does not expressly disclose the vehicle ingredients in the claim.

The secondary reference discloses optionally coated water-dispersible tablets to provide a tablet which is capable of dispersing in water within 3 minutes. The composition comprises inert ingredients such as microcrystalline cellulose, sodium glycolate of starch, polyvinylpyrrolidone, magnesium stearate and white opadry (abstract; claim 16). The reference does not disclose fluconazole and tinidazole.

It would have been obvious to one of ordinary skill in the art to add the vehicle ingredients in the secondary reference to the fluconazole and tinidazole in the primary reference. The motivation for doing so would have been the desire to make a water dispersible tablet which is capable of dispersing in water within a short period of time.

Claims 2, 3, 5, 18, 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cipla (Cipla: Therapeutic Index: Gynecological Products: Forcan TZ KIT: Fluconazole and Tinidazole: 2000) in view of Gillis et al. (Drugs. 1996 Apr; 51(4):621-38).

The disclosure and the rationale for the use of the primary reference are outlined above. The reference does not expressly disclose secnidazole.

The secondary reference discloses that secnidazole is structurally related to the commonly used 5-nitroimidazoles metronidazole and tinidazole. These drugs share a common spectrum of activity against anaerobic micro-organisms and they appear particularly effective in the treatment of amoebiasis, giardiasis, trichomoniasis and bacterial vaginosis (abstract).

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06 [R-6].

Generally, it is prima facie obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended purpose. See Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). See also In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). Accordingly, it would have been obvious to the secondary reference gives a list of several diseases the compounds are useful for; and would, therefore, provide reason for replacing on for the other in a composition.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cipla and Gillis et al., the combination taken in view of USP 5,660,860.

The disclosure and the rationale for the combination of the primary and secondary references are outlined above. The references do not expressly disclose the vehicle ingredients in the claim.

The tertiary reference discloses optionally coated water-dispersible tablets to provide a tablet which is capable of dispersing in water within 3 minutes. The composition comprises inert ingredients such as microcrystalline cellulose, sodium glycolate of starch, polyvinylpyrrolidone, magnesium stearate and white opadry (abstract; claim 16). The reference does not disclose fluconazole and tinidazole.

It would have been obvious to one of ordinary skill in the art to add the vehicle ingredients in the secondary reference to the fluconazole and secnidazole in the primary reference. The motivation for doing so would have been the desire to make a water dispersible tablet which is capable of dispersing in water within a short period of time.

Conclusion

No claims are allowed.

Pertinent art not relied upon for the present office action:

1. US 2003/0130225. The reference discloses an oral medication comprising fluconazole, which may be taken to treat a skin fungal infection with an approved dose such as about 150 mg or at a lower dose (¶ 0059). Other antimicrobials may be present in the composition such as secnidazole or tinidazole.

2. Malhotra et al. (Indian J of Medical Sciences (2003); 57(12):549-555). The Malhotra reference discloses the use of a kit containing fluconazole (150 mg), azithromycin (1 gm) and secnidazole (2 gm) as one time dose for the treatment of pelvic inflammatory disease (PID) (abstract).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chris E Simmons/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612